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## Brazil

## Biotechnology

## President Signs Regulatory Decree on Biosafety Law

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**Report Highlights:**

The President of Brazil, following eight months of intensive debate among several agencies of the federal government, signed Decree Number 5, 591 on November 23 that regulates the provisions of the Biosafety Law Number 11, 105 of March 24, 2005. Although, Decree Number 5,591 allows the National Technical Commission on Biosafety (CTNBio) to resume operations and evaluate nearly 500 requests for research and commercial approval of biotech products pending since March, there are several bureaucratic obstacles in the new Decree that likely will lead to major delays affecting companies involved in research and production.

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## Summary

After 8 months of intensive debate among government officials, President Lula signed and published on November 23, 2005, Decree Number 5, 591 that implements the provisions of the bio safety law 11,105, signed by him on March 24, 2005 after being enacted by the National Congress.

The long-awaited Decree will allow the National Technical Commission (CTNBio) to resume operations and begin to analyze nearly 500 requests for research and commercial approval of biotech products that have been pending since the Biosafety Law 11,105 was published on March 28, 2005.

*Note: In Brazil laws require a regulatory decree signed by the President in order to enter into effect. Although a Decree cannot change the principles of the law voted and approved by the National Congress, the Decree signed by the President (similar to an Executive Order in the United States) can create bureaucratic barriers or hurdles that may or may not contribute to the effectiveness of the law.*

## Main Points of Decree 5, 591

Main points of Decree 5,591/2005 signed by President of Brazil and published on November 23, 2005 that regulates the Biosafety Law Number 11,105, of January 12, 2005.

**CTNBio - Composition:** The National Technical Commission for Biosafety (CTNBio) will be composed of 27 members. Twelve of these members must be specialists (with doctorate education and recommended by scientific organizations). In addition, nine government officials will be appointed by the following agencies of the federal government: Ministry of Science and Technology (MCT), Ministry of Agriculture, Livestock, and Food Supply (MAPA), Ministry of Health (MS), Ministry of the Environment (MMA), Ministry of Development, Industry, and Foreign Trade (MDIC), Ministry of External Relations (MRE), Ministry of Agrarian Development (MDA), Ministry of Defense (MD), and Special Office of the President for Aquaculture and Fisheries. The remaining six members will be appointed as follows: one specialist in consumer rights by the Ministry of Justice; one specialist in human health by the Ministry of Health; one specialist in environment by the Ministry of the Environment; one specialist in biotechnology by the Ministry of Agriculture, Livestock and Food Supply; one specialist in family agriculture by the Ministry of Agrarian Development; one specialist in worker's health by the Ministry of Labor.

**CTNBio - DELIBERATIONS:** As a general rule, CTNBio decisions will be made by a majority vote of its members. However, there is a major exception regarding commercial approval of biotech products and their derivatives. In this case, CTNBio decision must be at least a two-thirds majority vote of its members (18 votes).

**CTNBio – Mandate:** Members of CTNBio can be appointed for two-year terms. Members may be reappointed for two additional consecutive periods. The Minister of Science will appoint the President of the CTNBio and Technology from a list of three names voted in the plenary assembly session of the Commission.

**CTNBio – Regular Meetings.** CTNBio will have monthly regular meetings, or may be convened in "extraordinary" sessions at any time, at the request of the President of CTNBio or by full majority of its members. A minimum quorum of 14 members is needed to invoke the meeting, including the mandatory presence of one specialist of each one of the following areas: animal and plant health, human health, and environment.

**CNBS – Purpose.** The National Biosafety Council (CNBS) was created by Law 11,105/05 and falls under the Executive Office of the President of the Republic. It is the highest-level advisory group of the President of the Republic regarding formulation and implementation of the National Biosafety Policy. Any appeal made to CNBS regarding the commercial use of biotech products will be evaluated and decided by 11 cabinet ministers based on social, economic, and national interests.

**CNBS – Composition.** The CNBS is composed of the following members: The Chief of Staff of the Presidency, who is the President of the Council; Minister of Science and Technology; Minister of Agrarian Development; Minister of Agriculture, Livestock, and Food Supply, Minister of Justice, Minister of Health; Minister of the Environment, Minister of Development, Industry, and Foreign Trade; Ministry of External Relations; Minister of Defense and the Special Secretary for Aquaculture and Fisheries of the Presidency. The Ministers listed above can be represented in the meetings by their Deputies, or by other legal substitute.

**CNBS – Deliberation.** CNBS decisions will be by a majority vote of its members and a minimum quorum of six members is necessary for any decision. CNBS will have 60 days to deliberate. Meantime, CTNBio's decisions will remain suspended until final decision by CNBS.

## Comments

The environmental community and other anti-biotech groups welcomed decree 5,591 because it increased to a two-thirds-majority vote CTNBio's mandate to approve commercial requests for use of biotech products. It represents a major victory for the Minister of the Environment who successfully lobbied President Lula to include several bureaucratic obstacles in the Decree, such as the two-thirds-majority vote, among other red tape.

Despite these administrative hurdles, the Ministry of Agriculture also welcomed the signing of Decree 5,591 by the President, because now there is a legal framework in place that will allow the development of biotech research in Brazil. Brazilian and multinational companies are now gearing up their technical departments to "fight", through CTNBio, for their requests for research and/or commercial use of their biotech products. According to the General Coordinator of the CTNBio, there are approximately 500 requests pending analysis and approval by the Commission. Among these requests, there are five requests for biotech corn already analyzed and pending final approval of CTNBio (two from Syngenta, one from Bayer, and two from Monsanto).

According to the General Coordinator of the CTNBio, agencies cited in the Decree 5,591 have until December 24, 2005 to name their representatives to be members of CTNBio. After these nominations are made, there is a legal time needed for publication in the Official Gazette (similar to the Federal Register in the United States). This means that CTNBio will likely be formed after the second week of January 2006. Then, there will be another legal period involved for the approval of the President of CTNBio. Only after all these names are approved and published in the Official Gazette can CTNBio legally meet to evaluate and approve pending requests filed at the Commission, such as those mentioned above. Some trade sources do not believe that CTNBio can meet before March 2006 because those anti-biotech groups headed by the Minister of the Environment will use the administrative obstacles in Decree 5,591 to delay nomination of members to the Commission.

## Informal Translation of Decree 5,591



Brazilian Presidency  
Civil Administration Office  
Sub-office for Legal Matters

## DECREE No. 5,591, OF NOVEMBER 22, 2005

Implements the provisions of Law No. 11,105, of March 24, 2005, which regulates Items II, IV, and V of Paragraph 1 of Article 225 of the Constitution, and other measures.

**The PRESIDENT OF BRAZIL**, using the authority conferred upon him by Article 84, Items IV and VI, Sub-item "a", of the Constitution, and in view of the provisions of Law No. 11,105, of March 24, 2005,

## DECREES:

CHAPTER I  
PRELIMINARY AND GENERAL PROVISIONS

Article 1. This Decree implements the provisions of Law No. 11,105, of March 24, 2005, which establishes safety rules and supervision mechanisms for the introduction, planting, production, manipulation, transportation, transfer, importation, exportation, storage, research, commercialization, consumption, release into the environment, and disposal of genetically modified organisms (GMOs) and derived products, and gives directives for the encouragement of scientific advancement in the area of biosafety and biotechnology, protection of life and human, animal and plant health, and compliance with the precautionary principle for environmental protection, and rules for the authorized use of embryo stem cells obtained from human embryos produced by in vitro fertilization and not used in the said procedure for purposes of research and therapy.

Article 2. The activities and projects that involve GMOs and derived products, related to education on the manipulation of living organisms, scientific research, technological development and industrial production are restricted to entities governed by public and private law that shall be responsible for compliance with the provisions of Law No. 11,105, 2005, this Decree and supplementary rules, and for possible consequences and effects of noncompliance.

Paragraph 1. For the purposes of this Decree, the entity's activities and projects are considered to be those conducted on the entity's premises or under the entity's administrative, technical, or scientific responsibility.

Paragraph 2. Individuals that are autonomous and independent, even if they have an employment relationship or any other relationship with legal entities shall not conduct the activities and projects regulated in this article.

Paragraph 3. Those interested in conducting an activity set forth in this Decree shall apply for an authorization from the National Technical Commission for Biosafety (CTNBio), which shall respond within the time set by law.

Article 3. For the purposes of this Decree, the following applies:

I - research activities: conducted in laboratory, containment regime, or field, during the process of obtaining GMOs and derived products or evaluating the biosafety of the GMO and derived products, which includes, in the experimental field, the introduction, planting, manipulation, transportation, transfer, importation, exportation, storage, release into the environment and disposal of the GMO and derived products;

II - activities of commercial use of GMOs and derived products: those not classified as research activities and which concerns the planting, production, manipulation, transportation, transfer, sale, importation, exportation, storage, consumption, release and disposal of GMOs and derived products for commercial purposes;

III - organism: every biological entity capable of reproducing or transferring genetic material, including viruses and other classes that may be discovered;

IV - deoxyribonucleic acid (DNA) and ribonucleic acid (RNA): genetic material that contains information that determines the hereditary characters transmittable to descendants;

V - molecules of recombinant DNA/RNA: molecules manipulated outside of living cells by the modification of segments of natural or synthetic DNA/RNA and which may multiply in a living cell, or also the molecules of DNA/RNA resulting from this multiplication; including the segments of synthetic DNA/RNA equivalent to natural DNA/RNA;

VI - genetic engineering: activity of producing and manipulating molecules of recombinant DNA/RNA;

VII - genetically modified organism (GMO): organism whose genetic material (DNA/RNA) has been modified by any genetic engineering technique;

VIII – GMO-derived: product derived from a GMO that has no autonomous capacity of replication or that does not contain a viable form of the GMO;

IX - human germ cell: mother-cell responsible for the formation of the gametes present in female and male sex glands and their direct descendants, to any degree of ploidy;

X - in vitro fertilization: the fusion of the gametes through any technique of extra corporeal fertilization;

XI - cloning: process of asexual reproduction, produced artificially, based on a single genetic heredity, with or without the utilization of techniques of genetic engineering;

XII - embryo stem cells: embryo cells capable of becoming cells of any tissue of an organism;

XIII - unviable embryos: those with genetic alterations proven by pre-implant diagnosis, according to specific rules established by the Ministry of Health, whose development was halted by the absence of spontaneous splitting, more than twenty-four hours after the in vitro fertilization, or with morphological alterations that compromised full development of the embryo;

XIV - available frozen embryo: those frozen up to March 28, 2005, after completion of three years from the date of freezing;

XV - genitors: final users of in vitro fertilization;

XVI - registration and supervision agencies and entities: those mentioned in the Main Provision of Article 53;

XVII - genetic technologies with restrictions on their use: any process of human intervention for the generation or multiplication of genetically modified plants to produce sterile reproductive structures, and any form of genetic manipulation intended for the activation or inactivation of genes related to the fertility of plants by external chemical inducers.

Paragraph 1. The category of GMO does not include the result from techniques that imply the direct introduction into an organism of hereditary material, if this does not involve the utilization of molecules of recombinant DNA/RNA or from a GMO, including in vitro fertilization, conjugation, transduction, transformation, polyploid induction, and any other natural process.

Paragraph 2. The category of GMO-derived product does not include chemically defined pure substances obtained by biological processes that do not contain GMOs, heterologous protein, or recombinant DNA.

## CHAPTER II THE NATIONAL TECHNICAL COMMISSION FOR BIOSAFETY

Article 4. CTNBio, under the Ministry of Science and Technology, is a multidisciplinary collective body of a deliberative and advisory nature, for the provision of technical support and advice to the Federal Government in the formulation, updating, and implementation of the National Biosafety Policy (PNB) for GMOs and derived products, and for establishing technical safety standards and technical opinions regarding the authorization of activities that involve research and commercial use of GMOs and derived products, based on the evaluation of the zoo phytosanitary risk to human health and to the environment.

Sole Paragraph. CTNBio shall supervise developments and technical and scientific progress in the fields of biosafety, biotechnology, bioethics and related matters, so as to increase its capacity to protect human, animal and plant life, and the environment.

### Section I Duties

Article 5. CTNBio shall:

- I - establish rules for research using GMOs and derived products;
- II - establish rules relating to the activities and projects involving GMOs and derived products;
- III - establish, within the scope of its powers, criteria for evaluating and monitoring the risks of GMOs and derived products;
- IV – perform risk assessment analysis, on a case-by-case basis, for activities and projects that involve GMOs and derived products;
- V - establish mechanisms for the operation of Internal Biosafety Commissions (CIBio), within the scope of each institution engaged in education, scientific research, technological development and industrial production that involve GMOs and derived products;
- VI - establish requirements related to biosafety for the authorization of operations by laboratories, institutions or companies engaged in activities relating to GMOs and derived products;
- VII - liaise with institutions engaged in the biosafety of GMOs and derived products, in Brazil and internationally;
- VIII - authorize, register and supervise research activities involving GMOs and derived products, according to the laws in force;
- IX - authorize importation of GMOs and derived products for research activities;
- X - provide advisory technical support and advice to the National Biosafety Council (CNBS) for the formulation of the National Biosafety Policy for GMOs and derived products;
- XI - issue Biosafety Quality Certificates (CQB) for the development of activities with GMOs and derived products in laboratories, institutions or companies, and send copies of the procedures to the registration and supervision agencies;
- XII - issue technical decisions, on a case-by-case basis, regarding the biosafety of GMOs and derived products, within the scope of the activities of research and commercial use of GMOs and derived products, including the classification of the degree of risk and level of biosafety required, and the safety measures required and restrictions on use;
- XIII - define the level of biosafety applicable to GMOs and their uses, and the respective procedures and safety measures for use, according to the rules set forth in this Decree, and for derived products;
- XIV - classify the GMO by risk class, according to the criteria established herein;
- XV - supervise the development and technical-scientific progress of biosafety for GMOs and derived products;
- XVI - issue normative resolutions about the matters under its authority;



XVII - provide technical support to the proper authorities for processes of prevention and investigation of accidents and diseases that are observed during the projects and activities using recombinant DNA/RNA techniques;

XVIII - provide technical support to the authorities and entities for registration and supervision, during the exercise of its activities relating to GMOs and derived products;

XIX – publish, in the Federal Official Gazette, summaries of claims before analysis and, subsequently, summaries of the opinions in the cases submitted to it, and provide wide-ranging publicity in the Biosafety Information System (SIB) about its agenda, pending cases, annual reports, minutes of meetings and other information about its activities, except for confidential information that is of commercial interest according to the applicant and so deemed by it;

XX - identify the activities and products resulting from the use of GMOs and derived products that are potential causes of environmental degradation or that may pose risks to human health;

XXI - reevaluate its technical decisions at the request of its members or on appeal from registration and supervision authorities and entities, on the grounds of new facts or scientific knowledge that are relevant for the biosafety of the GMO and derived products;

XXII - propose research and scientific studies in the field of biosafety of GMOs and derived products;

XXIII - present a draft of its internal regulations to the Ministry of Science and Technology.

Sole Paragraph. The revaluation provided for in Item XXI hereof shall be requested from the President of CTNBio in a petition containing the name and identification of the petitioner, the grounds accompanied by the description of the facts or report of the new scientific knowledge that supports the petition and the claim for a new decision about the biosafety of GMOs and derived products.

## Section II Membership

Article 6. CTNBio, composed of permanent and substitute members, appointed by the Minister of Science and Technology, shall be composed of twenty-seven Brazilian citizens of known technical competence and well-known work and scientific knowledge, with the academic degree of doctor and with prominent professional activity in the fields of biosafety, biotechnology, biology, human and animal health or the environment, of which:

I - twelve specialists of well-known scientific and technical knowledge, who are currently working, of whom:

- a) three in the field of human healthcare;
- b) three in the field of animals;
- c) three in the field of plants;

d) three in the field of the environment;

II - one representative of each of the following agencies, nominated by the respective office-holders:

- a) Ministry of Science and Technology;
- b) Ministry of Agriculture, Livestock-rearing and Supply;
- c) Ministry of Health;
- d) Ministry of the Environment;
- e) Ministry of Rural Development;
- f) Ministry of Development, Industry and Foreign Trade;
- g) Ministry of Defense;
- h) Foreign Ministry;
- i) Special Secretariat of Fishing of the Presidency of Brazil;

III - one specialist in consumer defense, appointed by the Minister of Justice;

IV - one specialist in healthcare, appointed by the Minister of Health;

V - one specialist in the environment, appointed by the Minister of the Environment;

VI - one specialist in biotechnology, appointed by the Minister of Agriculture, Livestock-rearing and Supply;

VII - one specialist in family farming, appointed by the Minister of Rural Development;

VIII - one specialist in workers' health, appointed by the Minister of Labor;

Sole Paragraph. Each permanent member has one substitute, who shall participate in the work in the absence of the permanent member.

Article 7. The specialists mentioned in Item I of Article 6 shall be chosen from a list of three permanent and substitute members.

Sole Paragraph. The Minister of Science and Technology shall institute an ad hoc commission, composed of members extraneous to CTNBio who are representatives of scientific societies, the Brazilian Society for the Progress of Science (SBPC) and the Brazilian Academy of Sciences (ABC), which shall prepare the list of three persons mentioned in the Main Provision of this Article, within thirty days after instituting the ad hoc commission.

Article 8. The representatives mentioned in Item II of Article 6 and their substitutes shall be appointed by the heads of the respective agencies within thirty days after the date of notice from the Minister of Science and Technology.

Article 9. The nomination of the specialists mentioned in Items III to VIII of Article 6 shall be made by the respective Ministers, from a list of three persons prepared by organizations within civil society endowed with legal personality that have a purpose that is compatible with the specialization set forth in those Items, in a procedure to be defined by the respective Ministries.

Article 10. The consultations with organizations within civil society, for the purposes of Article 9, shall be made no less than sixty days before the end of the term of office of the member to be replaced.

Article 11. The appointment of any member of CTNBio by reason of vacancy shall obey the same procedures applicable to ordinary appointment.

Article 12. CTNBio members shall hold office for two years, renewable for up to two consecutive periods.

Sole Paragraph. The computation of the term of office for the substitute member is continuous, even if he takes office permanently.

Article 13. Expenses on transportation, food and lodging for CTNBio members shall be borne by the Ministry of Science and Technology.

Sole Paragraph. The functions and activities performed by CTNBio members are considered to be highly important and honorable.

Article 14. CTNBio members shall abide by ethical-professional concepts, and they shall not participate in decision-making regarding issues with which they have any professional or personal involvement, under penalty of removal from office.

Paragraph 1. CTNBio members, upon their investiture, shall sign a declaration of conduct, indicating any possible conflict of interest, as provided for in the internal regulations.

Paragraph 2. CTNBio members shall declare their possible impediment in cases submitted for their analysis, upon receipt, or, when not the rapporteur, at the time of resolutions at the meetings of the subcommittees or the full board.

Paragraph 3. The impediment may be declared by the CTNBio member or by the interested party, as provided for in Article 9 of Law No. 9.784, of January 29, 1999.

Paragraph 4. The argument of impediment shall be formalized in a petition with statement of grounds and duly accompanied by evidence, and shall be decided by the full board of CTNBio.

Paragraph 5. The technical decision is null if the vote of the disqualified member was decisive.

Paragraph 6. The Full Board of CTNBio, when ruling on the impediment, shall enter a new technical decision, which shall expressly regulate the subject of the defective decision and the ensuing effects, since publication.

Article 15. The President of CTNBio and his substitute shall be appointed from among the members, by the Minister of Science and Technology, from a list of three persons voted by the full board.

Paragraph 1. The President of CTNBio shall hold office for two years, renewable for the same period.

Paragraph 2. The President of CTNBio shall, among other functions to be defined by the internal regulations:

I - represent CTNBio;

II - preside over the meeting of the full board of CTNBio;

III - delegate his functions;

IV - determine the provision of information and allow access to documents, as requested by the registration and supervision agencies.

### Section III Administrative Structure

Article 16. CTNBio has one Executive Secretary, and the Ministry of Science and Technology shall provide him with technical and administrative support.

Sole Paragraph. The Executive Secretary of CTNBio shall, among other functions to be defined by the internal regulations:

I - provide technical and administrative support to CTNBio members;

II - receive and prosecute the claims submitted to the resolution of CTNBio;

III - send the resolutions of CTNBio to the governmental agencies responsible for implementation and provide the publicity due;

IV - update the SIB.

Article 17. CTNBio shall constitute permanent sectoral subcommittees in the fields of human healthcare, animals and plants, and for the environment, and may constitute extraordinary subcommittees, for prior analysis of the subjects to be submitted to the full board.

Paragraph 1. Permanent and substitute members shall participate in the sectoral subcommittees, and the assignment of cases for analyses may be made to any of them.

Paragraph 2. The operation and coordination of the work of the sectoral and extraordinary subcommittees are defined in the internal regulations of CTNBio.

### Section IV Meetings and Resolutions

Article 18. The substitute member is entitled to speak and, in the absence of the respective permanent member, to vote at meetings.

Article 19. CTNBio meetings may be instituted with the presence of fourteen members, including at least one claimant from each field mentioned in Item I of Article 6.

Sole Paragraph. CTNBio decisions shall be made by an absolute majority of members, except for cases of commercial clearance of GMOs and derived products, in which case the decision shall be made by a supermajority of two-thirds of the members.

Article 20. Members shall be removed from office if they:

I - violate the provisions of Article 14;

II - fail to attend three consecutive regular meetings of the full board of CTNBio, without justification.

Article 21. CTNBio shall meet, regularly, once every month and, extraordinarily, at any moment, called by the President or upon justified request signed by an absolute majority of members.

Sole Paragraph. The periodicity of regular meetings may, exceptionally, be changed by a resolution from CTNBio.

Article 22. CTNBio meetings shall be recorded, and the respective minutes of decisions on claims shall contain a summary indicating the case number, the interested party, subject matter, reason for the decision, possible dissent and result.

Article 23. The summaries of claims shall be published in the Federal Official Gazette and in SIB at least thirty days before they are scheduled for decision, except for urgent cases, which shall be defined by the President of CTNBio.

Article 24. The summaries of opinions and the technical decisions shall be published in the Federal Official Gazette.

Sole Paragraph. The opinions with statement of reasons from each member shall be included in the SIB.

Article 25. The authorities and entities that belong to the federal government may request attendance at meetings of CTNBio to deal with matter of special interest to them, with no voting right.

Sole Paragraph. Requests to the Executive Secretary of CTNBio shall be accompanied by justification that demonstrates the reasons and proves the applicant's interest in biosafety of GMOs and derived products submitted to CTNBio.

Article 26. Representatives of the scientific community, the public sector and entities within civil society, with no voting rights, may be invited to attend meetings, exceptionally.

#### Section V Prosecution of Cases

Article 27. The cases within the scope of CTNBio, mentioned in Items IV, VIII, IX, XII, and XXI of Article 5, shall follow the procedure defined in this Section.

Article 28. The prior summary of the request filed with the Executive Secretary of CTNBio shall, after being recorded and duly explained, be published in the Federal Official Gazette and disclosed in SIB.

Article 29. The case shall be assigned to one permanent or substitute member, who shall report on it and prepare the opinion.

Article 30. The opinion shall be submitted to one or more permanent or extraordinary sectoral subcommittees to prepare and approve the final opinion.

Article 31. The final opinion shall, after approval by the sectoral or extraordinary subcommittees to which the case was assigned, be sent to the full board of CTNBio for a resolution.

Article 32. Dissenting opinions from members of the permanent or extraordinary sectoral subcommittee shall be presented expressly and with statement of reasons and shall be included as a dissenting opinion in the final opinion for consideration and resolution by the full board.

Article 33. Cases of commercial clearance of GMOs and derived products shall be submitted to all permanent subcommittees.

Article 34. The rapporteur of the opinions from subcommittees and the full board shall, in addition to the reports from the applicants, consider the existing scientific literature, and the studies and other documents filed at public hearings or at CTNBio.

Article 35. CTNBio shall adopt the measures necessary to protect confidential information of commercial interest, according to the applicant and so deemed by it, provided that such information is not subject to private or collective interests assured by the Constitution.

Paragraph 1. To ensure the secrecy mentioned in the Main Provision hereof, the applicant shall send to the President of CTNBio an express and justified request specifying the information to be kept confidential.

Paragraph 2. The claim shall be denied by an order with statement of reasons, which can be appealed against, to the full board, in a procedure to be established by the internal regulations of CTNBio, and the secrecy requested shall be assured until the final decision against it.

Paragraph 3. Applicants may choose to abandon the claim, if the request for confidentiality is definitively denied, in which event CTNBio shall not publicize the information that was the subject-matter of the confidentiality sought.

Article 36. The registration and supervision agencies and entities shall request access to confidential information, provided that it is indispensable for the exercise of their functions, by means of a petition justifying the claim and indicating the agent with access to it.

#### Section IV Technical Decision

Article 37. With regard to the biosafety aspects of GMOs and derived products, the technical decision from CTNBio is binding upon the other agencies and entities of the government.

Article 38. In cases of commercial use, the registration and supervision agencies shall, while exercising their functions in the event of request by CTNBio, give due regard to the technical decision from CTNBio concerning the biosafety aspects of GMOs and derived products, among other technical aspects of their analyses,

Article 39. In the event of a favorable technical decision regarding biosafety within the scope of the research activities, CTNBio shall send the respective case to the registration and supervision agencies and entities, so that they may discharge their functions.

Article 40. The technical decision from CTNBio shall contain a summary of the technical grounds, indicate the safety measures and restrictions on the use of GMOs and derived products and consider the particular features of the different regions of Brazil, in order to guide and support the registration and supervision authorities and entities while discharging their functions.

Article 41. Derived products for which the GMO has already been approved by CTNBio shall not be submitted to analysis and issuance of a technical opinion.

Article 42. Individuals or legal entities involved in any stage of the process of agricultural production, sale or transportation of genetically modified products in relation to which they obtained clearance for commercial use are exempt from the presentation of the CQB and constituting of a CIBio, unless otherwise decided by the CTNBio.

#### Section VII Public Hearings

Article 43. CTNBio may hold public hearings, thereby ensuring the participation of civil society, which shall be requested:

I - by one member and approved by an absolute majority, in any event;

II - by a party that gives evidence of interest in the subject-matter of the resolution and is approved by an absolute majority, in the case of commercial clearance.

Paragraph 1. CTNBio shall publish notices of public hearings in the SIB and Federal Official Gazette, at least thirty days in advance, indicating the subject-matter, date, time and place.

Paragraph 2. The public hearing shall be chaired by the President of CTNBio, who, after objectively explaining the subject-matter of the hearing, shall open the debate with the interested attendees.

Paragraph 3. After the completion of the work of the public hearing, the statements, opinions, suggestions and documents shall be made available for the interested parties at the Executive Secretariat of CTNBio.

Paragraph 4. The interested party is, for the purposes of Item II of the Main Provision hereof, the applicant of the case or a legal entity whose purpose is related to the fields set forth in the Main Provision and Items II, VII, and VIII of Article 6.

#### Section VIII General Rules for GMO Risk Classification

Article 44. For the classification of GMOs according to the risk classes, CTNBio shall consider, among other criteria:

- I - general characteristics of the GMO;
- II - vector characteristics;
- III - insertion characteristics;
- IV - characteristics of the donor and receptor organisms;
- V - product of the genetic expression of the sequences inserted;
- VI - activity proposed and the environment receiving the GMO;
- VII - proposed use of the GMO;
- VIII - adverse effects of the GMO on human health and on the environment.

#### Section IX Biosafety Quality Certificates

Article 45. Public or private institutions that intend to conduct research in laboratories, within containment regimes or in the field, during the process of obtaining a GMO or evaluation of the biosafety of the GMO, which includes, in the experimental field, the introduction, planting, manipulation, transportation, transfer, importation, exportation, storage, release into the environment and disposal of the GMO, shall request from CTNBio the issuance of a CQB.

Paragraph 1. CTNBio shall establish the criteria and procedures for the request, issuance, review, extension, suspension and cancellation of a CQB.

Paragraph 2. CTNBio shall send a copy of the issuance process for the CQB and updates to the registration and supervision agencies.

Article 46. Brazilian or foreign public and private organizations that finance or sponsor the activities or projects mentioned in the Main Provision of Article 2 shall request the presentation of a CQB, under penalty of becoming co-responsible for possible effects arising out of breach of this Decree.

Article 47. The cases not set forth in this Chapter shall be defined by the internal regulations of CTNBio.



CHAPTER III  
THE NATIONAL BIOSAFETY COUNCIL

Article 48. CNBS, which is connected to the Presidency of Brazil, is the highest advisory authority for aiding the President of Brazil in formulating and implementing the PNB.

Paragraph 1. CNBS shall:

I - set principles and guidelines for administrative actions by the federal agencies and entities with jurisdiction over the matter;

II - analyze, at the request of CTNBio, the aspects of convenience, socioeconomic opportunity and national interest of the applications for clearance for commercial use of GMOs and derived products;

III - call up and decide on the cases related to activities that involve the commercial use of GMO and derived products, as the ultimate and definitive level of jurisdiction, according to statements from CTNBio and, when deemed necessary, from the registration and supervision agencies and entities, within the scope of their jurisdictions.

Paragraph 2. Whenever CNBS approves the activity analyzed, it shall send its statement to the registration and supervision agencies and entities.

Paragraph 3. Whenever CNBS decides against the activity analyzed, it shall send its statement to CTNBio, to inform the applicant.

Article 49. CNBS is composed of the following members:

I - Minister of the Civil Administration Office of the Presidency of Brazil, who shall preside over it;

II - Minister of Science and Technology;

III - Minister of Rural Development;

IV - Minister of Agriculture, Livestock-rearing and Supply;

V - Minister of Justice;

VI - Minister of Health;

VII - Minister of the Environment;

VIII - Minister of Development, Industry and Foreign Trade;

IX - Foreign Minister;

X - Minister of Defense;

XI - Special Secretariat of Fishing of the Presidency of Brazil.

Paragraph 1. CNBS shall convene whenever called by its President or by a majority of members.

Paragraph 2. CNBS members are replaced, in their absences or impediment, by the respective Executive Secretaries or, in the absence of such office-holders, by their legal substitutes.

Paragraph 3. In the absence of the President, the President shall indicate a Minister to preside over the work.

Paragraph 4. CNBS meetings shall commence with the presence of at least six members and decisions shall be made by an absolute majority of members.

Paragraph 5. The internal regulations of CNBS shall define the procedures for the calling and holding of meetings and resolutions.

Article 50. CNBS shall decide, at the request of CTNBio, regarding the aspects of convenience, socioeconomic opportunity and national interest relating to clearance for commercial use of GMOs and derived products.

Paragraph 1. CTNBio shall file the full copy of the case relating to the activity to be analyzed, with the Executive Secretariat of CNBS, with indication of the reasons therefor.

Paragraph 2. The efficacy of the technical decision from CTNBio, if one had been entered in the specific case, shall be suspended until the final decision by CNBS.

Paragraph 3. CNBS shall rule on the applications for analysis mentioned in the Main Provision within sixty days, as from the date of filing of the application with the Executive Secretariat.

Paragraph 4. The time set forth in Paragraph 3 may be stayed until measures are taken or until the issuance of opinions by ad hoc consultants, as decided by CNBS.

Article 51. CNBS may call up the cases relating to activities that involve the commercial use of GMOs and derived products for analysis and decision, as the ultimate and definitive level of jurisdiction, within thirty days of the date of publication of the technical decision from CTNBio in the Federal Official Gazette.

Paragraph 1. CNBS may, when deemed necessary, request statements from the registration and supervision agencies and entities.

Paragraph 2. The technical decision from CTNBio shall be stayed until the expiration of the time set forth in the Main Provision, without the due mandate for the case, or until the final decision of CNBS, if it has called up the case.

Paragraph 3. CNBS shall make a decision within sixty days of the date of receipt by its Executive Secretariat of the full copy of the case called up.

Paragraph 4. The time set forth in Paragraph 3 may be stayed until measures are taken or until the issuance of opinions by ad hoc consultants, as decided by CNBS.

Article 52. CNBS shall decide the appeals from registration and supervision agencies and entities related to commercial clearance of GMOs and derived products that are filed with its Executive Secretariat, within thirty days of the date of publication of the technical decision from CTNBio in the Federal Official Gazette.

Paragraph 1. The appeals referred to in this Article shall be accompanied by a technical justification that demonstrates the divergence of the registration and supervision agency or entity, within the scope of their jurisdictions, in relation to the decision from CTNBio concerning the biosafety aspects of the GMO and derived products.

Paragraph 2. The efficacy of the technical decision from CTNBio shall be stayed until the expiration of the time set forth in the Main Provision, without the due filing of appeals by the supervision and registration agencies, or until the final decision by CNBS, if the appeal filed has been received and is being considered.

Paragraph 3. CNBS shall decide the appeal within sixty days of the date of filing with the Executive Secretariat.

Paragraph 4. The time set forth in Paragraph 3 may be stayed until measures are taken or until the issuance of opinions by ad hoc consultants, as decided by CNBS.

#### CHAPTER IV REGISTRATION AND SUPERVISION AGENCIES AND ENTITIES

Article 53. The registration and supervision agencies and entities of the Ministry of Health, Ministry of Agriculture, Livestock-rearing and Supply, and Ministry of the Environment, and of the Special Secretariat of Fishing of the Presidency of Brazil, among other functions and in accordance with their powers, the technical decision from CTNBio, the CNBS resolutions and the mechanisms established herein, shall:

- I - supervise the research activities involving GMOs and derived products;
- II - register and supervise the commercial clearance of GMOs and derived products;
- III - issue authorization for the importation of GMOs and derived products for commercial use;
- IV - establish rules for registration, authorization, supervision and environmental licensing of GMOs and derived products;
- V - supervise the enforcement of biosafety rules and measures established by CTNBio;
- VI - promote the training of supervisors and technicians in charge of the registration, authorization, supervision and environmental licensing of GMOs and derived products;
- VII - institute an internal committee specializing in the biosafety of GMOs and derived products;
- VIII - maintain up-to-date records in SIB regarding the enrollment of the institutions and technicians that conduct activities and projects related to GMOs and derived products;

IX - publish, including in SIB, the registrations, authorizations and environmental licenses granted;

X - apply the punishments set forth herein;

XI - support CTNBio in defining questions of biosafety evaluation for GMOs and derived products.

Paragraph 1. The rules mentioned in Item IV shall, when applicable, consist of compliance with the procedures, means and actions in force applicable to conventional products through the decisions from CTNBio.

Paragraph 2. After a favorable statement from CTNBio, or from CNBS, in the event of mandate or appeal, the following applies, as a consequence of the specific analysis and pertinent decision:

I - the Ministry of Agriculture, Livestock-rearing and Supply shall issue the authorizations and registrations, and supervise the products and activities that use GMOs and derived products intended for animal use, in agriculture, livestock-rearing, agribusiness and related areas, according to the laws in force and the rules that may be established;

II - the proper agency of the Ministry of Health shall issue the authorizations and registrations, and supervise the products and activities using GMOs and derived products intended for human use, pharmacy, sanitation and related areas, according to the laws in force and rules that may be established;

III - the proper agency of the Ministry of the Environment shall issue the authorizations and registrations, and supervise the products and activities that involve GMOs and derived products to be released into natural ecosystems, according to the laws in force and according to the rules that may be established, and the licensing for cases in which CTNBio decides that the GMO is a potential cause of significant environmental degradation, according to this Decree;

IV - The Special Secretariat of Fishing of the Presidency of Brazil shall issue the authorizations and registrations for products and activities involving GMOs and derived products intended for use in fishing, according to the laws in force and according to this Decree and the rules that may be established.

Article 54. CTNBio shall be the ultimate and definitive level of jurisdiction for decisions regarding cases in which the activity is a potential or actual cause of environmental degradation, and regarding the necessity for environmental licensing.

Article 55. The issuance of the registrations, authorizations and environmental licenses mentioned herein shall take place within one hundred and twenty days at the most.

Sole Paragraph. The computation of the time set forth in the Main Provision shall be stayed, for up to one hundred and eighty days, while the applicant prepares the necessary studies and explanations.

Article 56. The authorizations and registrations mentioned in this Chapter are bound by the corresponding technical decision from CTNBio, and technical requirements that

exceed the conditions established by that decision are prohibited, in matters relating to biosafety.

Article 57. The registration and supervision agencies and entities may establish joint actions to exercise their functions.

## CHAPTER V BIOSAFETY INFORMATION SYSTEM

Article 58. SIB, which is connected to the Executive Secretariat of CTNBio, is intended for managing the information on the activities of analysis, authorization, registration, monitoring and supervision of the activities that involve GMOs and derived products.

Paragraph 1. The provisions of legal acts, regulations and administrative acts that change, complement or produce effects on the biosafety laws for GMOs and derived products shall be disclosed in SIB simultaneously with the entry into force of these acts.

Paragraph 2. The registration and supervision agencies and entities shall feed SIB with the information relating to the activities set forth herein, processed within their scope of authority.

Article 59. CTNBio shall provide wide-ranging publicity for its activities by means of SIB, including its work agenda, calendar of meetings, cases pending, with the respective rapporteurs, annual reports, minutes of meetings and other information about its activity, except for confidential information of commercial interest that is considered as such by it.

Article 60. SIB shall enable electronic interaction between CNBS, CTNBio and the federal agencies and entities responsible for the registration and supervision of GMOs.

## CHAPTER VI INTERNAL BIOSAFETY COMMITTEES (CIBio)

Article 61. Institutions engaged in education, scientific research, technological development and industrial production that use techniques and methods of genetic engineering or perform research using GMOs and derived products, shall create an Internal Biosafety Committee (CIBio) whose mechanisms of operation shall be established by CTNBio.

Sole Paragraph. The institutions mentioned in the Main Provision of this Article shall indicate a principal technical expert responsible for each specific project.

Article 62. Within the scope of each institution, the CIBio shall:

I - keep the workers and other members of the community informed, when they may be affected by the activity, with regard to the issues relating to health and safety, and the procedures in the event of accidents;

II - establish preventive and inspection programs to ensure that CTNBio in accordance with the biosafety standards and rules defines the operation of the facilities under its responsibility;

III - send to CTNBio the documents required by CTNBio, for the purposes of analysis, registration or authorization by the proper authority, if applicable;

IV - maintain records of the individual follow-up for each ongoing activity or project that involves GMOs and derived products;

V - notify CTNBio, the registration and supervision agencies and entities and the workers' entities about the results from risk assessments applicable to the persons exposed, and any accidents or incidents that might cause the dissemination of a biological agent;

VI - investigate the occurrence of accidents and illnesses possibly related to GMOs and derived products and notify CTNBio about its conclusions and actions.

#### CHAPTER VII RESEARCH AND THERAPY USING HUMAN EMBRYO STEM CELLS OBTAINED BY IN VITRO FERTILIZATION

Article 63. The utilization of embryo stem cells obtained from human embryos produced by in vitro fertilization and not used in the respective procedure is permitted for the purposes of research and therapy, subject to the following conditions:

I - the embryos are unviable; or

II - the embryos are frozen and available.

Paragraph 1. In any event, the consent of the genitors is necessary.

Paragraph 2. Research institutions and health services that conduct research or therapy using human embryo stem cells shall submit their projects for consideration and approval by the respective research ethics committees, in accordance with the resolution from the National Health Council.

Paragraph 3. The sale of the biological material mentioned in this Article is prohibited, and such conduct is defined as a crime under Article 15 of Law No. 9,434, of February 4, 1997.

Article 64. The Ministry of Health shall make assessments and maintain up-to-date records of human embryos obtained by in vitro fertilization and not used in the respective procedure.

Paragraph 1. The institutions that perform activities that involve freezing and storing human embryos shall give the information necessary for identification of the unviable embryos produced in their establishments and of the available frozen embryos, in accordance with specific rules setting the times.

Paragraph 2. The Ministry of Health shall issue the rules mentioned in Paragraph 1 within thirty days after the publication hereof.

Article 65. The National Agency for Sanitary Surveillance (ANVISA) shall establish rules for the procedures of collection, processing, testing, storage, transportation, quality control and use of human embryo stem cells for the purposes of this Chapter.

Article 66. The genitors that give human embryo stem cells obtained according to the provisions of this Chapter, for purposes of research or therapy, shall sign a Statement of Informed Consent, according to the specific rule from the Ministry of Health.

Article 67. The utilization of human embryo stem cells for therapy, under Article 63, shall be conducted in accordance with the directives from the Ministry of Health for the evaluation of new technologies.

## CHAPTER VIII CIVIL AND ADMINISTRATIVE LIABILITY

Article 68. Without prejudice to the application of the penalties set forth in Law No. 11,105, of 2005, and in this Decree, those responsible for damage to the environment and to third parties shall be jointly and severally liable for compensation or full redress, irrespective of the existence of fault.

### Section I Administrative Violations

Article 69. An administrative violation is any action or omission that violates the rules of Law No. 11,105, of 2005, and of this Decree and other pertinent legal provisions, especially:

I – conducting of activities or projects that involve GMOs and derived products, relating to education with the manipulation of living organisms, scientific research, technological development and industrial production as a self-employed individual;

II – conducting of activities of research and commercial use of GMOs and derived products without authorization from CTNBio or in breach of the rules issued by it;

III - failure to require the presentation of the CQB issued by CTNBio to the legal entity that finances or sponsors activities and projects that involve GMO and derived products;

IV - use, for purposes of research and therapy, of embryo stem cells obtained from human embryos produced by in vitro fertilization without the consent of the genitors;

V – conducting of activities of research or therapy with human embryo stem cells without the approval of the respective research ethics committee, as regulated by the National Health Council;

VI – selling of embryo stem cells obtained from human embryos produced by in vitro fertilization;

VII - use, for purposes of research and therapy, of embryo stem cells obtained from human embryos produced by in vitro fertilization in breach of the provisions of Chapter VII;

VIII - failure to maintain records of the individual follow-up for each ongoing activity or project that involves GMOs and derived products;

IX – conducting of genetic engineering on a living organism in breach of the rules of this Decree;

X – conducting of in vitro handling of natural or recombinant DNA/RNA in breach of the rules set forth in this Decree;

XI – conducting of genetic engineering on human germ cells, human zygotes and human embryos;

XII – conducting of human cloning;

XIII - destruction or release into the environment of GMOs and derived products in breach of the rules established by CTNBio, registration and supervision agencies and entities and this Decree;

XIV - release into the environment of GMOs and derived products, within the scope of research activities but without a favorable technical decision from CTNBio, or in breach of the rules hereof;

XV - release into the environment of GMOs and derived products, within the scope of commercial activities but without a license from the environmental authority in charge, when CTNBio has deemed that the activity is a potential cause of environmental degradation;

XVI - release into the environment of GMOs and derived products, within the scope of commercial activities but without approval from CNBS, when it called up the case;

XVII - use, sale, registration, patenting or licensing of genetic technologies with restrictions on their use;

XVIII - failure by the institution to send investigation reports on accidents that occur during the course of research and projects involving genetic engineering, within a maximum of five days following the date of the event;

XIX - failure by the institution to immediately notify CTNBio and the public health, farming protection and environmental authorities regarding an accident that may cause the dissemination of GMOs and derived products;

XX - failure by the institution to adopt the means necessary to fully inform CTNBio, the public health, environmental and farming protection authorities, the community and the other employees of the institution or company, regarding the risks to which they may be subjected, and the procedures to be taken in the event of accidents with GMOs and derived products;

XXI - failure to create a CIBio in conformity with the rules from CTNBio, by an institution that uses techniques and methods of genetic engineering or that performs research using GMOs and derived products;

XXII – maintaining a CIBio in operation in breach of the rules from CTNBio;

XXIII - failure by the institution to keep the workers and other members of the community informed, by means of the CIBio, when they may be affected by the activity, in relation to the health and safety issues and the procedures in the event of accidents;



XXIV - failure by the institution to establish preventive and inspection programs, through the CIBio, to ensure the operation of the facilities under its responsibility, in accordance with the biosafety standards and rules defined by CTNBio;

XXV - failure by the institution to notify CTNBio, the registration and supervision agencies and entities and the workers' entities, through the CIBio, regarding the results from risk assessments applicable to the persons exposed, and regarding any accidents or incidents that may cause the dissemination of a biological agent;

XXVI - failure by the institution to investigate the occurrence of accidents and illnesses possibly related to GMOs and derived products and to notify CTNBio regarding its conclusions and actions;

XXVII - production, storage, transportation, sale, importation or exportation of GMOs and derived products, without authorization or in breach of the rules established by CTNBio and the registration and supervision agencies and entities.

## Section II Administrative Sanctions

Article 70. Administrative violations, irrespective of the provisional remedies of seizure of products, suspension of the sale of products, and suspension of activities, shall be subject to the following sanctions:

I - warning;

II - fine;

III - seizure of the GMO and derived products;

IV - suspension of the sale of GMO and derived products;

V - suspension of the activity;

VI - partial or total interdiction of the establishment, activity, or undertaking;

VII - suspension of registration, license or authorization;

VIII - cancellation of registration, license or authorization;

IX - loss or restriction of incentive and tax benefit granted by the government;

X - loss or suspension of participation in a line of credit through an official credit establishment;

XI - intervention in the establishment;

XII - prohibition of entering into contracts with the government, for up to five years.

Article 71. For the imposition of the punishment and its magnitude, the registration and supervision agencies and entities shall take into account:

I - the seriousness of the violation;

II - past compliance by the violator with agricultural, sanitary, environmental and biosafety rules;

III - economic advantage obtained by the violator;

IV - economic situation of the violator.

Sole Paragraph. For the purposes of Item I, the violations set forth in this Decree shall be classified as petty, serious and very serious, according to the following criteria:

I - the Risk Classification of the GMO;

II - the means used to commit the violation;

III - the actual and potential consequences to human dignity, to human, animal and plant health, and to the environment;

IV - the culpability of the violator.

Article 72. The warning shall apply only to petty violations.

Article 73. The fine shall apply according to the following grades:

I - from two thousand *Reais* (R\$ 2,000.00) to sixty thousand *Reais* (R\$ 60,000.00) for petty violations;

II - from sixty thousand and one *Reais* (R\$ 60,001.00) to five hundred thousand *Reais* (R\$ 500,000.00) for serious violations;

III - from five hundred thousand and one *Reais* (R\$500,001.00) to one million five hundred thousand *Reais* (R\$ 1,500,000.00) for very serious violations.

Paragraph 1. Double fine shall apply in the event of recurrence.

Paragraph 2. Fines may apply cumulatively with the other sanctions set forth herein.

Article 74. The fines set forth in Law No. 11,105, of 2005, and in this Decree shall be applied by the registration and supervision agencies and entities, in accordance with their respective jurisdictions.

Paragraph 1. The funds derived from the application of fines shall be sent to the registration and supervision agencies and entities that imposed the fine.

Paragraph 2. The supervisory agencies and entities of the federal government may enter into agreements with the States, Federal District, and Municipalities, for them to carry out the services relating to the supervision activities set forth herein, and the amounts derived from the imposition of fines may be transferred.

Article 75. The sanctions set forth in Items III, IV, V, VI, VII, IX, and X of Article 70 shall apply only to serious or very serious violations.

Article 76. The sanctions set forth in Items VIII, XI, and XII of Article 70 shall apply only to very serious violations.

Article 77. If the infractor simultaneously commits two or more violations, it shall be subject cumulatively to the sanctions applicable to each violation.

Article 78. In the event of continued violation, characterized by the continuation of the action or omission initially punished, the respective punishment shall apply on a daily basis until the cause ceases, without prejudice to the immediate suspension of the activity or interdiction of the laboratory or institution or company responsible.

Article 79. The registration and supervision agencies and entities may, irrespective of the application of administrative sanctions, impose provisional remedies of seizure of products, suspension of the sale of products, and suspension of activities, if there is imminent risk of harm to human dignity, to human, animal and plant health, and to the environment.

### Section III Administrative Proceedings

Article 80. Any person may, after observing the occurrence of an administrative violation, send a complaint to the proper supervisory authority, for the purposes of having supervisory powers exercised.

Article 81. Administrative violations shall be investigated by separate administrative proceedings that assure the right to full defense and adversarial proceedings.

Article 82. The employees of the supervisory agencies set forth in Article 53 are the authorities competent to issue the notice of violation, institute the administrative proceedings and indicate the punishment applicable.

Article 83. The supervisory authority shall send a copy of the notice of violation to CTNBio.

Article 84. When the violation is a crime, misdemeanor, or injury to the Public Treasury or consumers, the supervisory authority shall send a complaint to the proper authority for investigating the administrative and criminal liability.

Article 85. This Decree is subject to the provisions of Law No. 9,784, 1999, as the case may be.

### CHAPTER IX FINAL AND TRANSITORY PROVISIONS

Article 86. CTNBio shall, within ninety days of its institution, define:

I – a draft of its internal regulations, to be submitted for approval by the Minister of Science and Technology;

II – the risk classes for GMOs;

III - the biosafety levels applicable to GMOs and derived products, according to the risk classes for GMOs.

Sole Paragraph. Before CTNBio defines the risk classes for GMOs, the table in the Annex to this Decree shall apply, for the purposes of classification.

Article 87. The Executive Secretary of CNBS shall submit the draft of the internal regulations to the board within ninety days.

Article 88. GMOs that obtained technical decisions from CTNBio in favor of their commercial clearance up to March 28, 2005, may be registered and sold in accordance with CNBS Resolution No. 1, of May 27, 2005.

Article 89. Institutions that perform activities regulated by this Decree shall conform to its provisions within one hundred and twenty days as from the publication hereof.

Article 90. Law No. 7,802, of July 11, 1989, does not apply to GMOs and derived products, except for their development to serve as a raw material for agrochemical production.

Article 91. Food products and food ingredients intended for human or animal consumption that contain or that are made of GMOs and derived products shall contain information about this on their labels, in accordance with the specific decree.

Article 92. CTNBio shall promote review and, if necessary, adaptation of CQB's in relation to communications, technical decisions and normative acts issued under Law No. 8,974, of January 5, 1995, if they do not conform to Law No. 11,105, of 2005, and to this Decree.

Article 93. CTNBio and the registration and supervision agencies and entities shall review their normative resolutions within one hundred and twenty days as from the publication hereof, to promote their adequacy to the provisions hereof.

Article 94. This Law takes effect on the date of its publication.

Article 95. Decree No. 4,602, of February 21, 2003 is hereby repealed.

Brasília, November 22, 2005; 184<sup>th</sup> year since Independence, and 117<sup>th</sup> year since the Republic.

LUIZ INÁCIO LULA DA SILVA  
*Roberto Rodrigues*

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This text does not replace the text published in the Federal Official Gazette on November 23, 2005.

**ANNEX**  
**Risk Classification of Genetically Modified Organisms**

Risk Class I: includes the organisms that satisfy the following criteria:

## A. Receiving or parental organism:

- non-pathogenic;
- exempt from adventitious agents;
- with broad documented history of safe utilization, or incorporation of biological barriers that, without interfering in optimal growth in the reactor or fermentation vessel, allows limited survival and multiplication, without negative effects on the environment;

## B. Vector/insertion:

- must be adequately characterized and without known harmful sequences;
- the size must be limited, insofar as possible, to the genetic sequences necessary to conduct the designed function;
- cannot increase the stability of the modified organism in the environment;
- must be almost incapable of mobilization;
- cannot transmit any marker of resistance to organisms that, according to the knowledge available, do not acquire it naturally;

## C. Genetically modified organisms:

- non-pathogenic;
- present the same level of safety as does the receiving or parental organism in the reactor or fermentation vessel, but with limited survival or multiplication, without negative effects on the environment;

D. Other genetically modified organisms that could be included in Risk Class I, provided that they satisfy the conditions set forth in Item C above:

- micro organisms built entirely from one single prokaryotic receptor (including plasmid and endogenous viruses) or from one single eukaryotic receptor (including its chloroplasts, mitochondria and plasmids, but excluding viruses), and organisms composed entirely of genetic sequences from different species that exchange such sequences through known physiological processes;

Risk Class II: all those not included in Risk Class I.